



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Our Ref: 1038-384 MIS:tc

Patent application

No. 08/286,189

Applicant: Sonia E. Sanhueza et al

Title: INACTIVATED RESPIRATORY SYNCYTIAL

VIRAL

VACCINES

Filed: August 5, 1994

Group No. 1648

Examiner: B. Nelson

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GROUP 1800

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REQUEST FOR RECONSIDERATION OF FINAL REJECTION

BY COURIER

The Commissioner of Patents  
and Trademarks,  
Washington, D.C. 20231,  
U.S.A.

Dear Sir:

This communication is in response to the Final Action of February 13, 1998. Reconsideration is requested for the following reasons.

The Examiner indicated that Applicants have prematurely filed the Notice of Appeal and Appeal Brief without allowing reexamination to take place. While the Office Action of November 26, 1996 was not specifically indicated to be Final, the claims were rejected for a second time under 35 U.S.C. 103 and 37 C.F.R. 1.191(a) permits an Appeal to be lodged from a second rejection of the claims on the same ground, even though non-Final.

In any event, the Examiner has now issued a Final Rejection, noting that applicant's amendment of April 23, 1997 is being treated under 35 U.S.C. 132 as a request for reconsideration and that applicants are entitled to a refund for any fees paid for the Notice of Appeal and Appeal Brief. The Examiner specifically

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(W.D.)

withdrew all prior rejections in view of the Amendments made to the claims and entered a new ground of rejection.

The Examiner rejected claims 1, 3 to 9 and 11 to 16 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most closely connected, to make and/or use the invention. Reconsideration is requested.

In particular, the Examiner states in the Final Action that

"The specification shows inactivated RSV, which has been inactivated by n-octyl- $\beta$ -D-glucopyranoside,  $\beta$ -propiolactone, or ascorbic acid, and which elicits antibody production in cotton rats."

The Examiner further states in the Final Action that:

"The specification provides no probative evidence to support the claimed vaccine which would protect humans against RSV. In order to enable claims to drugs and their uses, either in vivo or in vitro data, or a combination of these can be used. However, the data must be such as to convince one of ordinary skill in the art that the claims are fully enabled. When the claims are directed to humans, adequate animal data would be acceptable in those instances wherein one of ordinary skill in the art would accept the correlation to humans. Thus in order to rely on animal data there must exist an art-recognized animal model for testing purposes."

After a highly selective discussion of the literature, the Examiner concludes in the Final Action that:

"...it appears that the cotton rat data does not correlate to humans and the cotton rat is not an art accepted model for vaccine evaluation with regards to RSV in humans and particularly infants."

The Examiner characterizes the rejection as a new one and yet this rejection has been made and overcome previously. In this regard, reference is made to the Office Action of October 5, 1995 wherein the Examiner stated:

"...protection observed in the cotton rat model cannot be extrapolated to humans. Due to the

unpredictability of RSV vaccines to provide protection in humans, it would require undue experimentation to determine how to use the claimed vaccine compositions to provide protection in humans."

The applicants submitted considerable arguments in response for this rejection. The second action merely repeated the comments of the Examiner in the first action without any explanation as to why applicant's arguments were in some manner defective. After re-submission of the arguments, the Examiner stated in the Office Action of November 26, 1996:

"In view of applicant's amendments and arguments, claims 1 to 16 rejected under 35 U.S.C.112, first paragraph has been withdrawn". (emphasis added)

The Examiner persisted with rejection under 35 U.S.C. 103 in that Office Action whereupon followed applicant's amendment of April 23, 1997.

In the latest Office Action, the Examiner specifically withdrew the prior art rejection, the only outstanding rejection and reinstated rejection under 35 U.S.C. 112, first paragraph, on grounds already withdrawn. The Examiner does not explain this apparent anomaly, nor why the arguments presented earlier and previously considered sufficient, no longer are considered sufficient. The applicants are, once again, required to present an argument already considered to be sufficient to overcome the issue of compliance with 35 U.S.C. 112, first paragraph.

It would seem that the Examiner's action is unduly burdensome on applicants. It would not appear fruitful to reiterate this argument in this paper but rather refer the Examiner's attention to the relevant arguments presented earlier. The Examiner's attention is directed in this regard to pages 5 to 9 of the Amendment of April 4, 1996, and to pages 3 to 4 of the Amendment of October 3, 1996, copies of which are appended hereto and incorporated herein by reference.

Having regard thereto it is submitted that the rejection of claims 1, 3 to 9 and 11 to 16 under 35 U.S.C. 112, first paragraph, should be withdrawn, just as

it was earlier in the prosecution. Since the Examiner indicates that the claims are free of the prior art, it would appear that the claims are in an allowable form.

It is believed that this application now is in condition for allowance and early and favourable consideration and allowance are respectfully solicited.

Respectfully submitted,



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